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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/215,435	12/17/98	EDWARDS J	GENSET.019A

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EXAMINER	
LONGTON, E	
ART UNIT	PAPER NUMBER
1653	16

DATE MAILED: 06/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/215,435	Edwards et al.
Examiner	**Group Art Unit**
Enrique D. Longton	1653

☒ Responsive to communication(s) filed on *Apr 18, 2000* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) *9-12, 15, 17, and 20* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-8, 13, 14, 16, 18, and 19* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *11,15*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Status of the Claims

Claims 1-8, 13, 14, 16, 18 and 19 have been elected in Paper No. 12 without traverse. Applicants have selected SEQ ID NOs:66, 71, 76, 78, 113, 116, 117, 118, 123 and 124 for examination. Claims 9-12, 15, 17 and 20 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority Dates for the Selected SEQ ID NOs

Applicants indicate in Table 1, beginning on page 150 of the specification, the following priority dates for the selected sequences:

Sequence	Priority Date
SEQ ID NO:66	8/10/98
SEQ ID NO:71	8/10/98
SEQ ID NO:76	12/17/97
SEQ ID NO:78	8/10/98
SEQ ID NO:113	2/9/98
SEQ ID NO:116	2/9/98
SEQ ID NO:117	4/13/98
SEQ ID NO:118	4/13/98
SEQ ID NO:123	2/9/98
SEQ ID NO:124	4/13/98

Objections to the Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821(d). Applicant is reminded that sequence(s) disclosed in the specification must be identified by SEQ ID NO(s). Specifically, the sequences shown in figure 9 are not properly identified in the figure or the brief description of the figure by SEQ ID NO. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 4, 5, 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3, 4, 5, 7 and 8 are directed to polynucleotides encoding the full coding sequences including the signal peptides and/or mature proteins corresponding to the disclosed polynucleotides. Beginning on page 136 and continuing through page 147, some of the polynucleotides of the invention and the encoded proteins are described. No indication exists in

this or any other part of the specification which would guide the person wishing to practice the invention such that he would know what the mature forms of the proteins are or which portion(s) constitute signal peptides. There are no coding sequences disclosed in the specification which have been identified as full-length or mature. Furthermore, no signal or leader sequences which may be cleaved post-translationally from the proteins have been disclosed. As the claims are currently written, the mature forms of the proteins are described as single, undefined polypeptides, yet no indication has been made in the specification as to what these polypeptides might be, whether or not they differ from the sequences disclosed in the specification or what modifications must be made such that the mature forms would result. Examiner notes that there is precedence in the prior art for full-length unprocessed proteins to be processed into more than one unique compound. Applicants have not disclosed whether the instant proteins have only a single precursor form or whether they go through several rounds of signal sequence processing to produce a mature form as is the case with, for example Neurophysin I and II, which are produced from prepropressophysin and prepro-oxyphysin, respectively (Ganong, Figure 14-11), or cholecytokinin-pancreozymin (CCK) which undergoes multiple processing steps such that prepro-CCK is processed into many fragments (Ganong, p. 446). Since neither the signal peptides nor the mature forms of the proteins have been disclosed in the specification, a person skilled in the art would not recognize that Applicants were in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 13, 14, 16, 18 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The claimed polynucleotides are not supported by either a specific and substantial asserted utility or a well established utility because the specification fails to assert any utility for the claimed polynucleotides or the encoded proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed polynucleotides or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility cannot be assessed.

Claims 1-8, 13, 14, 16, 18 and 19 are directed to polynucleotides comprising or related to SEQ ID NOs:66, 71, 76, 78, 113, 116, 117, 118, 123 and 124 or various subsequences of these polynucleotides. The claims do not meet the utility requirement because no activity is associated with the encoded proteins. Applicants, in their response, are required to clearly set forth what specific activity is associated with each of the 10 polynucleotides and the encoded polypeptides. Applicants assert that based on various alignments with database submissions, the claimed polynucleotides may share some unspecified activity with these submissions. The alignments have

not been provided and no percent similarity is disclosed. Based on the specification, it is unclear what activity the claimed polynucleotides possess, what activity the encoded proteins or protein fragments possess or how a person having skill in the art might use the claimed polynucleotides. It would require undue experimentation for a person having skill in the art to be able to use the claimed polynucleotides because the specification discloses no specific activity for the polynucleotides or the encoded proteins and no guidance has been given for the selection of an assay to determine what biological activity, if any, the claimed polynucleotides or encoded proteins possess. It is *a priori* unpredictable based on the instant disclosure what activity the claimed polynucleotides possess because no correlation has been made between the claimed polynucleotides and a specific activity. Therefore, without more, it would require undue experimentation for a person having skill in the art to practice the claimed invention.

Nowhere in the specification do Applicants make a positive declarative statement of a specific biological activity associated with the claimed polynucleotides beyond an assertion that the polynucleotides may encode proteins that may be secreted.

The assertions of general utility made by Applicants in the specification are not sufficient to meet the requirements of 35 USC 101 or 35 USC 112, first paragraph. The M.P.E.P. at 2107a provides guidance on how the Office is to interpret assertions of utility:

> Practical considerations require the Office to rely on the inventor's understanding of his or her invention in determining whether and in what regard an invention is believed to be "useful." Because of this, Office personnel should focus on and be receptive to specific assertions made by the applicant that an invention is "useful" for a particular reason. Office personnel should distinguish between situations where an applicant has

> disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a "useful" invention may arise from what has been disclosed by the applicant. Knapp v. Anderson , 477 F.2d 588, 177 USPQ 688 (CCPA 1973).
>
> Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific utility based on the setting in which the invention is to be used. One example are inventions to be used in a research or laboratory setting. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the specific invention is in fact "useful" in a patent sense. Instead, Office personnel must distinguish between inventions that have a specifically identified utility and inventions whose specific utility requires further research to identify or reasonably confirm. Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific utility for the invention.

In the instant case, the failure of Applicants to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101 and 35 USC 112, first paragraph. No specific biological activity has been identified for the encoded proteins or for the polynucleotides encoding the proteins other than the fact that the proteins may be secreted. The person having ordinary skill in the art would not be able to identify any specific activity for the proteins based on their structure alone for the reasons set forth above. General

statements that a composition has an unspecified biological activity or that do not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

Claims 1-8, 13, 14, 16, 18 and 19 are also rejected under 35 USC 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Stryer *et al.* (1981) The Stryer reference teaches trinucleotide codons which are complementary to the claimed polynucleotide sequences. Examiner note that no length limitation has been placed on the

complementary sequences of the claim. Inserting the word "fully" before the word "complementary" would overcome this rejection. Therefore, the claim is anticipated by the reference.

Claims 2, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by EST sequence with Accession No. R55298, Hillier *et al.* (22-May-1995) as evidenced by the alignment of SEQ ID NO:66 with the EST.

Claims 2, 18 and 19 are directed to polynucleotides having at least 10 or at least 15 contiguous nucleotides of SEQ ID NO:66. The reference discloses an EST sequence having greater than 15 contiguous nucleotides identical to the claimed SEQ ID NO. Therefore, the claim is anticipated by the reference.

Claims 2, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by EST sequence with Accession No. G13307, Hudson (04-June-1996) as evidenced by the alignment of SEQ ID NO:71 with the EST.

Claims 2, 18 and 19 are directed to polynucleotides having at least 10 or at least 15 contiguous nucleotides of SEQ ID NO:71. The reference discloses an EST sequence having greater than 15 contiguous nucleotides identical to the claimed SEQ ID NO. Therefore, the claim is anticipated by the reference.

Claims 2, 18 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by EST sequence with Accession No. B46318, Mahairas *et al.* (21-Oct-1997) as evidenced by the alignment of SEQ ID NO:76 with the EST.

Claims 2, 18 and 19 are directed to polynucleotides having at least 10 or at least 15 contiguous nucleotides of SEQ ID NO:76. The reference discloses an EST sequence having greater than 15 contiguous nucleotides identical to the claimed SEQ ID NO. Therefore, the claim is anticipated by the reference.

Claims 2, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by EST sequence with Accession No. AA230943, Marra *et al.* (26-Feb-1997) as evidenced by the alignment of SEQ ID NO:78 with the EST.

Claims 2, 18 and 19 are directed to polynucleotides having at least 10 or at least 15 contiguous nucleotides of SEQ ID NO:78. The reference discloses an EST sequence having greater than 15 contiguous nucleotides identical to the claimed SEQ ID NO. Therefore, the claim is anticipated by the reference.

Claims 2, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by EST sequence with Accession No. AA338114, Adams *et al.* (21-April-1997) as evidenced by the alignment of SEQ ID NO:113 with the EST.

Claims 2, 18 and 19 are directed to polynucleotides having at least 10 or at least 15 contiguous nucleotides of SEQ ID NO:113. The reference discloses an EST sequence having greater than 15 contiguous nucleotides identical to the claimed SEQ ID NO. Therefore, the claim is anticipated by the reference.

Claims 2, 18 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by EST sequence with Accession No. AA452724, Hillier *et al.* (05-June-1997) as evidenced by the alignment of SEQ ID NO:116 with the EST.

Claims 2, 18 and 19 are directed to polynucleotides having at least 10 or at least 15 contiguous nucleotides of SEQ ID NO:116. The reference discloses an EST sequence having greater than 15 contiguous nucleotides identical to the claimed SEQ ID NO. Therefore, the claim is anticipated by the reference.

Claims 2, 18 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by EST sequence with Accession No. AA397836, Hillier *et al.* (16-May-1997) as evidenced by the alignment of SEQ ID NO:118 with the EST.

Claims 2, 18 and 19 are directed to polynucleotides having at least 10 or at least 15 contiguous nucleotides of SEQ ID NO:118. The reference discloses an EST sequence having greater than 15 contiguous nucleotides identical to the claimed SEQ ID NO. Therefore, the claim is anticipated by the reference.

Claims 2, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by EST sequence with Accession No. AA040832, Hillier *et al.* (30-Aug-1996) as evidenced by the alignment of SEQ ID NO:123 with the EST.

Claims 2, 18 and 19 are directed to polynucleotides having at least 10 or at least 15 contiguous nucleotides of SEQ ID NO:123. The reference discloses an EST sequence having greater than 15 contiguous nucleotides identical to the claimed SEQ ID NO. Therefore, the claim is anticipated by the reference.

Claims 2, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by EST sequence with Accession No. W37255, Hillier *et al.* (10-Oct-1996) as evidenced by the alignment of SEQ ID NO:124 with the EST.

Claims 2, 18 and 19 are directed to polynucleotides having at least 10 or at least 15 contiguous nucleotides of SEQ ID NO:124. The reference discloses an EST sequence having greater than 15 contiguous nucleotides identical to the claimed SEQ ID NO. Therefore, the claim is anticipated by the reference.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Enrique D. Longton whose telephone number is (703) 305-4062. The Examiner can normally be reached from 7:45 a.m. to 4:15 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via

the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Enrique D. Longton, Ph.D.
June 16, 2000

ENRIQUE D. LONGTON
PATENT EXAMINER